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| 10/528,875 | 03/23/2005 | Janet A. Halliday | 4017-003 | 8764 |
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| Law Office of John K. Pike, PLLC 2121 Eisenhower Avenue, Suite 200 Alexandria, VA 22314 | | | EXAMINER | |
| | | | SASAN, ARADHANA | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,875

Applicant(s)

HALLIDAY ET AL.

Examiner

ARADHANA SASAN

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) 7 and 14-20 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 8-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 23 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/23/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Restriction Response

1. Applicant's election without traverse of Group I (claims 1-13) and the species elections of polyethylene glycol as the polyethylene oxide, decane-1,10-diol as the difunctional compound, and dicyclohexyl methane-4,4-diisocyanate as the difunctional diisocyanate in the reply filed on 08/19/08 are acknowledged.
2. Claim 7 is drawn to non-elected species of the difunctional compound.
3. Claims 7 and 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.
4. Claims 1-6 and 8-13 are included in the prosecution.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 03/23/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fildes et al. (US 4,202,880).

The claimed invention is a water-swellaable linear polymer obtainable by reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional isocyanate.

Fildes teaches a linear copolymer, "substantially devoid of cross-linking, and consisting of a plurality of hydrophilic and hydrophobic regions, and wherein the hydrophilic regions are composed of one or more polyoxyalkylene(s) containing the repeating unit $-(CH_2)_2O-$, $-CH_2CH(CH_3)O-$, $-(CH_2)_3O-$ and/or $-(CH_2)_4O-$, and the hydrophobic regions are composed of a polyurethane which is obtainable in known general manner from a diisocyanate and one or more dihydroxy compounds ..." (Col. 1, line 64 to Col. 2, line 8). Polyethylene glycol (molecular weight ca. 4000) is used as the polyoxyalkylene component (Col. 4, lines 30-31). 4, 4'-Diphenylmethane diisocyanate is mixed with diethylene glycol, 1,2-propylene glycol and 1,3-butyleneglycol (Col. 4, lines 35-38).

Regarding instant claim 1, the limitation of a liner polymer is anticipated by the linear polymer taught by Fildes (Col. 1, line 64 to Col. 2, line 8). The limitation of reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional isocyanate is anticipated by the linear copolymer comprising a mixture of polyethylene glycol, 4, 4'-Diphenylmethane diisocyanate and diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol, as taught by Fildes (Col. 4, lines 26-38).

Regarding instant claims 2-3, the limitation of the polyethylene oxide with a number average molecular weight of 4000 to 35,000 is anticipated by the polyoxyethylene of molecular weight 400 to 20,000 (Col. 2, lines 40-42).

Therefore, the limitations of claims 1-3 are anticipated by the teachings of Fildes.

9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (Biomaterials 1991 Vol. 12 March, pages 119-120).

Yu teaches a polymer "prepared from a high molecular weight poly(ethylene glycol) of $M_n=5830$ and a low molecular weight poly(propylene glycol) (PPG-425), with the polyurethaneurea chain extension carried out with 4,4'-dicyclohexylmethane diisocyanate and 4,4'-diphenylmethane diamine" (Page 120, left hand column, under Materials and Methods).

Regarding instant claim 1, the limitation of a liner polymer obtained by reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional

isocyanate is anticipated by the polymer taught by Yu (Page 120, left hand column, under Materials and Methods).

Regarding instant claims 2-3, the limitation of the polyethylene oxide with a number average molecular weight of 4000 to 35,000 is anticipated by the poly(ethylene glycol) of $M_n=5830$, as taught by Yu (Page 120, left hand column, under Materials and Methods).

Regarding instant claim 4, the limitation of the difunctional compound as a diamine is anticipated by the 4,4'-diphenylmethane diamine, as taught by Yu (Page 120, left hand column, under Materials and Methods).

Therefore, the limitations of claims 1-4 are anticipated by the teachings of Yu.

10. Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. (WO 94/22934).

Graham teaches the synthesis of a linear block copolymer comprising polyethylene glycol (average number molecular weight within a range of 5000-7000), polypropylene glycol, dicyclohexylmethane 4,4'-di-isocyanate, 4,4'-diaminodiphenylmethane and anhydrous ferric chloride (Page 14, Example 1, line 10 to Page 17, line 14). Graham teaches that the polyurethaneurea hydrogels are soluble in certain organic solvents including dichloromethane (Page 17, lines 10-12).

Regarding instant claim 1, the limitation of a liner polymer obtained by reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional

isocyanate is anticipated by the polymer taught by Graham (Page 14, Example 1, line 10 to Page 17, line 14).

Regarding instant claims 2-3, the limitation of the polyethylene oxide with a number average molecular weight of 4000 to 35,000 is anticipated by the polyethylene glycol (average number molecular weight within a range of 5000-7000), as taught by Graham (Page 14, lines 16-21).

Regarding instant claim 4, the limitation of the difunctional compound as a diamine is anticipated by the 4,4'-diaminodiphenylmethane, as taught by Graham (Page 15, lines 2-5).

Regarding instant claim 13, the limitation of the polymer being soluble in dichloromethane is anticipated by the polyurethaneurea hydrogels that soluble in certain organic solvents including dichloromethane, as taught by Graham (Page 17, lines 10-12).

Therefore, the limitations of claims 1-4 and 13 are anticipated by the teachings of Graham.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fildes et al. (US 4,202,880) in view of Wunder et al. (US 3,639,157).

The teaching of Fildes with respect to the linear copolymer of polyethylene glycol, a diisocyanate and one or more dihydroxy compounds is stated above.

Fildes does not expressly teach a diamine, a diol or decane-1,10-diol (elected species) as the difunctional compound.

Wunder teaches coating textiles with polyurethanes (Col. 1, lines 48-52). Polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate are disclosed along with combination of the isocyanate with the polyol (Col. 2, lines 1-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a linear copolymer with polyethylene glycol, a diisocyanate and polyols, as suggested by Fildes, combine it with the polyurethane of polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate, as suggested by Wunder, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Wunder teaches that the polyurethane includes suitable polyols such as polyethylene glycol, suitable polyhydric alcohols such as 1,10-decane diol and suitable isocyanates such as 4,4'-dicyclohexyl methane diisocyanate (Col. 2, lines 1-40).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a linear polymer is taught by the linear polymer taught by Fildes (Col. 1, line 64 to Col. 2, line 8). The limitation of reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional isocyanate is taught by the linear copolymer comprising a mixture of polyethylene glycol, 4, 4'-Diphenylmethane diisocyanate and diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol, as taught by Fildes (Col. 4, lines 26-38).

Regarding instant claims 2-3, the limitation of the polyethylene oxide with a number average molecular weight of 4000 to 35,000 is taught by the polyoxyethylene of molecular weight 400 to 20,000 (Col. 2, lines 40-42).

Regarding instant claims 4-6, the limitation of the difunctional compound as a diamine or diol would have been obvious over the 1,10-decane diol taught by Wunder (Col. 2, lines 7-12).

Regarding instant claims 8-12, the limitations of the ratio of components (a) to (b) to (c) and the limitations of the polymer's water swellability would have been obvious over the mixture of polyethylene glycol, 4, 4'-Diphenylmethane diisocyanate and diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol, as taught by Fildes (Col. 4, lines 26-38) in view of the polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate taught by Wunder (Col. 2, lines 1-40). Fildes teaches that "the degree of hydrophilicity, and therefore of water-swellability, of the copolymer can be pre-determined by its composition" (Col. 1, lines 50-52). Therefore, one of ordinary skill

in the art would vary the ratio of these components during the process of routine experimentation in order to achieve the desired degree of hydrophilicity or water swellability. The recited ratio of components (a) to (b) to (c) and the recited percentages of the polymer's water swellability would have been obvious variants unless there is evidence of criticality or unexpected results.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fildes et al. (US 4,202,880) in view of Wunder et al. (US 3,639,157 and further in view of Graham et al. (WO 94/22934).

Fildes and Wunder do not specifically teach the solubility of the polymer in dichloromethane.

Graham teaches that the polyurethaneurea hydrogels are soluble in certain organic solvents including dichloromethane (Page 17, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a linear copolymer with polyethylene glycol, a diisocyanate and polyols, as suggested by Fildes, combine it with the polyurethane of polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate, as suggested by Wunder, test the solubility of the polymer in organic solvents such as dichloromethane, as evidenced by Graham, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Fildes teaches that the polymer is soluble in common organic solvents (Col. 1, lines 40-45). One of ordinary skill in the art would know that dichloromethane is a commonly

used organic solvent, as evidenced by the teaching of Graham. One of ordinary skill in the art would therefore find it obvious to test the solubility of the linear polymer in dichloromethane during the process of routine experimentation.

Conclusion

14. No claims are allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615